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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/360,934 07/26/99 COVACCI

A CHIR-0158

EXAMINER

BUI, P

ART UNIT	PAPER NUMBER
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1645

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DATE MAILED:

02/07/00

HM12/0207
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/360,934

Applicant(s)

Covacci et al.

Examiner

Phuong Bui

Group Art Unit

1645



☒ Responsive to communication(s) filed on Jul 26, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 38-50 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 38-50 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☒ received in Application No. (Series Code/Serial Number) 08/256,848.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Sequence compliance

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of preliminary amendment A, Paper No. 2, filed July 26, 1999. Claims 38-50 are pending and are examined in the instant application.

Drawings

2. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

3. Applicant is required to update the status of the priority and continuing applications as applicable in the first line of the specification.

35 U.S.C. 112, second paragraph

4. Claims 40-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

“Substantially” is a relative term lacking a comparative basis.

By “an effective amount”, it is unclear what effect is desired, i.e., effective for what purpose?

Clarification and/or correction are required.

35 U.S.C. 112, first paragraph

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5. Claims 40-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claims which recite "exhibits substantially no contribution to toxicity", Applicant is invited to point to the page and line number in the specification where support for such recitation can be found.

In claims which specify "five to about fifteen amino acids", fifteen amino acids is taught as a lower limit and not as an upper limit as used here (see p. 14, ln. 25-27). Amending the above phrase to "five to at least fifteen amino acids" would obviate this rejection.

6. Claims 40-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:3, does not reasonably provide enablement for an amino acid sequence which "exhibits substantially no contribution to toxicity" or the "prophylactic or therapeutic vaccine" recitation in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Applicant does not teach any five, ten or fifteen amino acids of SEQ ID NO:3 which is effective for use as a vaccine. The vaccine use implies that the polypeptide would elicit a protective immune response in administered animals when challenged with wildtype *H. pylori*. The state of the prior art does not teach which polypeptides/proteins are effective for use as a vaccine against *H. pylori*. The current state of the art as of the date of this writing indicates that a mucosal adjuvant is required for vaccine efficacy of *H. pylori* component

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vaccines. Furthermore, even if a five, ten or fifteen amino acids of SEQ ID NO:3 is effective for use as a vaccine, Applicant provided no guidance as to which amino acids of SEQ ID NO:3 would be effective, or how one skilled in the art would be able to eliminate inoperable embodiments without excessive burden and undue experimentation. Applicant also does not teach which five, ten or fifteen amino acids of SEQ ID NO:3 “exhibits substantially no contribution to toxicity”. It was not known in the prior art at the time the invention was made which region of SEQ ID NO:3 contributes to toxicity. It is unpredictable based upon Applicant’s disclosure as to which five, ten or fifteen amino acids of SEQ ID NO:3 would or would not contribute to toxicity. Accordingly, Applicant has not enabled the invention as commensurate in scope with the claims.

35 U.S.C. 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 38-49 are rejected under 35 U.S.C. 102(a) as being anticipated by Applicant’s admitted prior art Cover et al. (J. Biol. chem. 267:10570-75, 1992 (U)). On page 6 of the specification, Applicant states that the 87 kDa protein results from either the further processing of the 100 kDa protein of the instant invention or from proteolytic degradation of a larger protein during purification. Thus the scope of the claims encompasses the 87 kDa protein of Cover,

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which would inherently be a portion of SEQ ID NO:3. The vaccine use holds little weight in the patentability of the product. Since the 87 kDa protein of Cover was used to raise antiserum, the 87 kDa protein must have been in a pharmaceutically acceptable carrier. Accordingly, the claimed invention is anticipated by Cover.

Remarks

9. No claims are allowed.


10. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1645, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (703) 305-1996. The Examiner can normally be reached Monday-Friday from 6:30 AM - 4:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui
Patent Examiner
Group Art Unit 1645
February 6, 2000


PHUONG T. BUI
PATENT EXAMINER